



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

SEP - 8 2000 5 6 3 1 '00 OCT -3 P2:33

Mr. Jim Roza
Director, Quality Assurance
NOW Foods
395 S. Glen Ellyn Road
Bloomingdale, Illinois 60108

Dear Mr. Roza:

This is in response to your letter of June 27, 2000 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Now Foods is making the following claim, among others, for the product **Glucose Metabolic Support**:

“...support healthy blood sugar levels...”

“...support healthy blood sugar levels and natural insulin production”

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for this product suggests that it is intended to treat, prevent, cure or mitigate diseases, namely disorders related to blood glucose levels. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely,

John B. Foret
Director
Division of Compliance and Enforcement
Office of Nutritional Products, Labeling,
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

975-0163

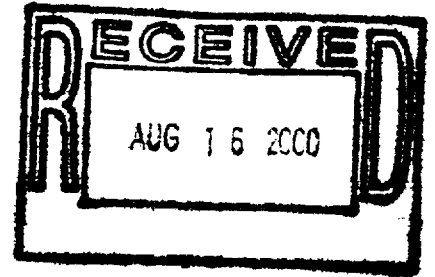
LET 387



The Future of Natural Foods

June 27, 2000

Office of Special Nutritionals (HF-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street SW
Washington, DC 20204



Re: 21 U.S.C. Section 343(r)(6), Notification of Statements on Dietary Supplements

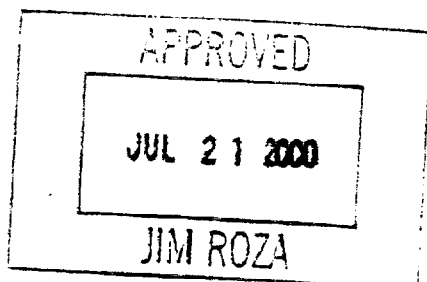
Dear Sir/Madam:

I hereby notify the Food and Drug Administration ("FDA") of the use of statements of nutritional support in the labeling of Glucose Metabolic Support, a blood sugar regulation product.

Statements being made in the labeling of Glucose Metabolic Support

- (1) Glucose Metabolic Support contains Glucosol™, a new dietary ingredient extracted from the herb *Lagestroemia speciosa*. Glucosol™'s active component, corosolic acid, has been the subject of scientific studies that show it may support healthy blood sugar levels by facilitating the transport of glucose into cells. We have also included an extract from the herb *Gymnema sylvestre*, a small plant native to India. Extracts of *Gymnema* have been used for centuries by Ayurvedic medical practitioners to support healthy blood sugar levels and natural insulin production.

To the best of my knowledge, and based upon information and belief present at the time of the executing of this notice, I certify that the above information is accurate and complete. NOW Foods possesses substantiation that the statements are truthful and not misleading.



Jim Roza
Director, Quality Assurance
NOW Foods
395 S. Glen Ellyn Rd.
Bloomington, IL 60108

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